Charles M. Lizza
William C. Baton
SAUL EWING LLP
One Riverfront Plaza
Newark, NJ 07102
(973) 286-6700

*Attorneys for Plaintiff Sepracor Inc.*

*Of Counsel*:

Joseph M. O'Malley, Jr.
Bruce M. Wexler
David M. Conca
Eric W. Dittmann
Lynn M. Terrebonne
PAUL, HASTINGS, JANOFSKY & WALKER LLP
75 East 55th Street
New York, NY 10022
(212) 318-6000

**UNITED STATES DISTRICT COURT**
**DISTRICT OF NEW JERSEY**

| | |
|---|---|
| **SEPRACOR INC.,**<br><br>**Plaintiff,**<br><br>**v.**<br><br>**TEVA PHARMACEUTICALS USA, INC., *et al.*,**<br><br>**Defendants.** | **Civil Action No. 09-1302 (DMC)(MF)**<br><br>**Hon. Dennis M. Cavanaugh, U.S.D.J.**<br>**Hon. Mark Falk, U.S.M.J.**<br><br>**(Filed Electronically)** |

**SEPRACOR'S REPLY TO ANSWER AND COUNTERCLAIMS OF WOCKHARDT LTD. AND WOCKHARDT USA, LLC**

Plaintiff Sepracor Inc. ("Sepracor") hereby replies to the numbered paragraphs of the counterclaims of Defendants Wockhardt Ltd. ("Wockhardt Ltd.") and Wockhardt USA, LLC ("Wockhardt USA") (collectively, "Wockhardt") set forth in Wockhardt's "Answer and Counterclaims" filed on May 5, 2009 (D.I. 35), as follows:

**COUNTERCLAIMS**

1. Wockhardt repeats and incorporates by reference each of the foregoing paragraphs of Wockhardt's Answer and Additional Defenses to the Complaint.

**RESPONSE:** Sepracor reasserts and realleges its averments set forth in its complaint and incorporates them by reference herein.

2. This is an action for a declaratory judgment of non-infringement, invalidity, and/or unenforceability of United States Patent No. 6,444,673 ("the '673 patent") under 35 U.S.C. § 271(e)(5), 28 U.S.C. §§ 2201(a) and (b), and/or 21 U.S.C. § 355(j). A true and correct copy of the '673 patent is attached hereto as Exhibit A.

**RESPONSE:** Sepracor admits that Wockhardt has asserted a counterclaim for declaratory judgment. Sepracor denies that Wockhardt is entitled to any such relief.

**The Parties**

3. Wockhardt USA, LLC is a corporation organized under the laws of the state of Delaware, having a principal place of business at 20 Waterview Boulevard, Parsippany, NJ 07054. Wockhardt Ltd. is an Indian corporation having a principal place of business at Wockhardt Towers, Bandra-Kurla Complex, Bandra (East), Mumbai, Maharashtra 400 051.

**RESPONSE:** Sepracor admits the allegations set forth in paragraph 3.

4. On information and belief, Sepracor is a corporation organized and existing under the laws of the state of Delaware, having a principal place of business at 84 Waterford Drive, Marlborough, MA 01752.

**RESPONSE:** Sepracor admits the allegations set forth in paragraph 4.

5. This Court has subject matter jurisdiction over these Counterclaims for declaratory judgment pursuant to 35 U.S.C. § 271(e)(5); 28 U.S.C. §§ 1331, 1337(a), 1338(a) and (b), 2201(a) and (b), 2202; and/or 21 U.S.C. § 355(j), based on an actual controversy between Wockhardt and Sepracor arising under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*

**RESPONSE:** Sepracor admits that this Court has subject matter jurisdiction based on an actual and justiciable controversy between Wockhardt and Sepracor concerning Wockhardt's generic eszopiclone products sufficient to invoke the subject matter jurisdiction of the Court. Sepracor denies the remaining allegations set forth in paragraph 5.

6. This Court has personal jurisdiction over Sepracor based, inter alia, on the filing by Sepracor of this lawsuit in this jurisdiction.

**RESPONSE:** Sepracor does not contest personal jurisdiction in this Court for the purposes of this action only, and otherwise denies the allegations set forth in paragraph 6.

7. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and 1400(b).

**RESPONSE:** Sepracor does not contest venue in this Court for the purposes of this action only, and otherwise denies the allegations set forth in paragraph 7.

**Orange Book Listing of the '673 Patent**

8. On information and belief, Sepracor is the assignee of the '673 patent.

**RESPONSE:** Sepracor admits the allegations set forth in paragraph 8.

9. On information and belief, pursuant to 21 U.S.C. § 355(b)(1)(G), Sepracor caused the FDA to publish the '673 patent in the Orange Book in connection with NDA No. 21-476.

**RESPONSE:** Sepracor admits that the '673 patent is listed in the Orange Book in relation to Lunesta®. Sepracor denies the remaining allegations set forth in paragraph 9.

10. By maintaining the listing of the '673 patent in the Orange Book, Sepracor represents that the '673 patent "could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use or sale of the drug." 21 U.S.C. § 355(b)(1)(G).

**RESPONSE:** Paragraph 10 contains allegations of law to which no response is required. Sepracor further responds that Wockhardt's characterization of the law is incomplete and/or inaccurate and, to the extent a response is required, otherwise denies the remaining allegations set forth in paragraph 10.

**Wockhardt's Abbreviated New Drug Application**

11. Wockhardt filed ANDA No. 91-165 ("the Wockhardt ANDA") with the FDA seeking approval to market its proposed eszopiclone oral tablets in 1 mg, 2 mg, and 3 mg strengths. Wockhardt certified to the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (referred to as a "Paragraph IV certification") and 21 C.F.R. § 314.95, that the '673 patent is

invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale and/or offer for sale of Wockhardt's proposed eszopiclone tablets.

**RESPONSE:** Based on information and belief, Sepracor understands that Wockhardt filed an ANDA (No. 91-165) seeking approval to market 1 mg, 2 mg and 3 mg eszopiclone tablets prior to the expiration of the '673 patent. Sepracor denies the remaining allegations set forth in paragraph 11.

12. In accordance with the requirements of 21 U.S.C. § 355(j)(2)(B), Wockhardt mailed Sepracor a notice letter stating that it had filed ANDA No. 91-165, containing a Paragraph IV certification regarding the '673 patent and offering Sepracor confidential access to ANDA No. 91-165. Sepracor accepted and agreed to an offer of Confidential Access regarding ANDA No. 91-165, and Wockhardt provided Sepracor with information from Wockhardt's ANDA.

**RESPONSE:** Sepracor admits the allegations set forth in paragraph 12.

**The Existence of a Justiciable Controversy**

13. Wockhardt's Paragraph IV certifications state that the '673 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale and/or offer for sale of Wockhardt's proposed eszopiclone tablets.

**RESPONSE:** Sepracor admits that Wockhardt's notice letter alleges that the '673 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, and/or offer for sale of Wockhardt's proposed eszopiclone tablets. Sepracor denies that the '673 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, and/or offer for sale of Wockhardt's proposed eszopiclone tablets.

14. In response to Wockhardt's ANDA and Paragraph IV certifications against the '673 patent, Sepracor filed this infringement action under 35 U.S.C. § 271(e)(2)(A), asserting the '673 patent, thus gaining the exclusionary benefit of an automatic 30-month stay of approval of Wockhardt's ANDA.

**RESPONSE:** Paragraph 14 contains allegations of law to which no response is required. Sepracor further responds that Wockhardt's characterization of the law is incomplete and/or

inaccurate and, to the extent a response is required, Sepracor admits that it filed an action alleging that Wockhardt infringes the '673 patent and denies the remaining allegations set forth in paragraph 14.

15. Wockhardt has not stipulated to or otherwise consented to the validity, infringement, or enforceability of the '673 patent.

**RESPONSE:** Sepracor lacks knowledge sufficient to form a belief as to the allegations set forth in paragraph 15, and, therefore, denies them.

16. If Wockhardt succeeds in proving that the '673 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale and/or offer for sale of Wockhardt's proposed eszopiclone tablets, such a judgment will remove any independent barriers to competition that may exist by virtue of Sepracor's maintenance of the listing of the '673 patent in the Orange Book in connection with NDA No. 21-476.

**RESPONSE:** Paragraph 16 contains allegations of law to which no response is required. Sepracor further responds that Wockhardt's characterization of the law is incomplete and/or inaccurate and, to the extent a response is required, otherwise denies the remaining allegations set forth in paragraph 16.

17. In light of all the circumstances, an actual substantial and continuing justiciable controversy having sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Sepracor and Wockhardt as to whether the '673 patent is invalid, unenforceable and/or not infringed by Wockhardt.

**RESPONSE:** Sepracor admits there is an actual and justiciable controversy between Wockhardt and Sepracor concerning Wockhardt's generic eszopiclone products. Sepracor denies the remaining allegations set forth in paragraph 17.

**FIRST COUNT**

**(Declaratory Judgment of Invalidity, United States Patent No. 6,444,673)**

18. Wockhardt repeats and incorporates by reference each of the foregoing paragraphs of Wockhardt's Answer and Defenses to the Complaint and of these Counterclaims.

**RESPONSE:** Sepracor reasserts and realleges its averments set forth above in response to the foregoing paragraphs, as well as the averments set forth in its complaint and incorporates them by reference herein.

19. An actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Sepracor and Wockhardt concerning the invalidity of claims of the '673 patent.

**RESPONSE:** Sepracor admits there is an actual and justiciable controversy between Wockhardt and Sepracor concerning Wockhardt's generic eszopiclone products. Sepracor denies the remaining allegations set forth in paragraph 19.

20. Claims of the '673 patent are invalid for failure to comply with the requirements of patentability as specified in 35 U.S.C. §§ 1 *et seq.*, including, without limitation, 35 U.S.C. §§ 101, 102, 103, 112 and/or 120, and/or based on other judicially-created bases for invalidation.

**RESPONSE:** Sepracor denies the allegations set forth in paragraph 20.

21. Thus, Wockhardt is entitled to a declaratory judgment that claims of the '673 patent are invalid.

**RESPONSE:** Sepracor denies the allegations set forth in paragraph 21.

**SECOND COUNT**

**(Declaratory Judgment of Non-Infringement, United States Patent No. 6,444,673)**

22. Wockhardt repeats and incorporates by reference each of the foregoing paragraphs of Wockhardt's Answer and Defenses to the Complaint and of these Counterclaims.

**RESPONSE:** Sepracor reasserts and realleges its averments set forth above in response to the foregoing paragraphs, as well as the averments set forth in its complaint and incorporates them by reference herein.

23. A case of actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Sepracor and Wockhardt concerning the noninfringement of claims of the '673 patent.

**RESPONSE:** Sepracor admits there is an actual and justiciable controversy between Wockhardt and Sepracor concerning Wockhardt's generic eszopiclone products. Sepracor denies the remaining allegations set forth in paragraph 23.

24. Wockhardt's manufacture, use, offer for sale, sale and/or importation into the United States of eszopiclone tablets pursuant to ANDA No. 91-165 will not infringe any valid and enforceable claim of the '673 patent.

**RESPONSE:** Sepracor denies the allegations set forth in paragraph 24.

25. Thus, Wockhardt is entitled to a declaratory judgment that Wockhardt's eszopiclone tablets will not infringe any valid and enforceable claim of the '673 patent.

**RESPONSE:** Sepracor denies the allegations set forth in paragraph 25.

## THIRD COUNT

**(Declaration Of Unenforceability of the '673 Patent)**

26. Wockhardt repeats and incorporates by reference each of the foregoing paragraphs of Wockhardt's Answer and Defenses to the Complaint and of these Counterclaims.

**RESPONSE:** Sepracor reasserts and realleges its averments set forth above in response to the foregoing paragraphs, as well as the averments set forth in its complaint and incorporates them by reference herein.

27. As set forth below, Wockhardt is entitled to a declaration that the '673 patent is unenforceable due to inequitable conduct in prosecuting the '673 patent before the PTO.

**RESPONSE:** Sepracor denies the allegations set forth in paragraph 27.

**Inequitable Conduct**

28. On information and belief, Sepracor, the inventors of the '673 patent, and/or other persons substantively involved in prosecuting the '673 patent engaged in a pattern of intentionally deceptive conduct throughout the prosecution of the family of applications that resulted in issuance of the '673 patent. The conduct was designed to maximize Sepracor's patent protection over its eszopiclone product eventually marketed as Lunesta®. Upon information and belief, those substantively involved in prosecuting the family of applications that resulted in issuance of the '673 patent participated in this scheme at the direction of, with the knowledge of, and/or on behalf of Sepracor. In addition to the evidentiary support detailed below, further evidentiary support for this allegation is likely to be identified after a reasonable opportunity for further investigation and discovery.

**RESPONSE:** Sepracor denies the allegations set forth in paragraph 28.

29. In violation of their duty of candor to the PTO, those substantively involved in the prosecution of the family of applications that resulted in issuance of the '673 patent intentionally misled the PTO by making material misstatements and misrepresentations in support of patentability.

**RESPONSE:** Sepracor denies the allegations set forth in paragraph 29.

30. Prosecuting a patent application is an ex parte process and, therefore, the law imposes a duty of good faith, candor, and disclosure on everyone associated with prosecuting the application. See 37 C.F.R. §1.56; Manual of Patent Examining Procedure (MPEP) § 2000.

**RESPONSE:** Paragraph 30 contains allegations of law to which no response is required. Sepracor further responds that Wockhardt's characterization of the law is incomplete and/or inaccurate and, to the extent a response is required, denies the remaining allegations set forth in paragraph 30.

31. The duty of good faith, candor, and disclosure requires, inter alia, the applicant, his agents, attorneys, and anyone else substantively involved in the prosecution of an application disclose all information material to patentability. See Section 2001.06 of the MPEP.

**RESPONSE:** Paragraph 31 contains allegations of law to which no response is required. Sepracor further responds that Wockhardt's characterization of the law is incomplete and/or inaccurate and, to the extent a response is required, denies the remaining allegations set forth in paragraph 31.

32. Information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and (1) it establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or (2) it refutes, or is inconsistent with, a position the applicant takes in: (i) opposing an argument of unpatentability relied on by the Office, or (ii) asserting an argument of patentability. Moreover, information is material to patentability if a reasonable patent examiner would have considered such information important in deciding whether to allow an application.

**RESPONSE:** Paragraph 32 contains allegations of law to which no response is required. Sepracor further responds that Wockhardt's characterization of the law is incomplete and/or inaccurate and, to the extent a response is required, denies the remaining allegations set forth in paragraph 32.

33. The '673 patent claims a chemical compound, namely the dextrorotatory isomer of zopiclone, and pharmaceutical compositions containing that compound.

**RESPONSE:** Paragraph 33 contains allegations of law to which no response is required. Sepracor further responds that Wockhardt's characterization of the law is incomplete and/or inaccurate and, to the extent a response is required, denies the remaining allegations set forth in paragraph 33.

34. The named inventors of the '673 patent, the individuals who submitted Declarations to the PTO during prosecution of the '673 patent, the attorneys and patent professionals at the law firm(s) prosecuting the family of applications that resulted in issuance of the '673 patent, Sepracor and/or Rhone-Poulenc Rhorer in-house business, legal and/or technical staff involved in efforts to obtain the '673 patent and/or other substantively-involved persons to be identified after further investigation and discovery (collectively "the '673 patent applicants") asserted, in the '673 patent specification and during prosecution of the family of applications resulting in issuance of the '673 patent, that the claims of the '673 patent were patentable because the dextrorotatory isomer of zopiclone (also referred to as eszopiclone, the (+) isomer, or

the s-isomer), possessed a surprising and unexpected property. The '673 patent applicants made these assertions with knowledge of highly material information which refuted, and was inconsistent with, these assertions, but they never disclosed this highly material information to the PTO.

**RESPONSE:** Sepracor admits the invention claimed in the '673 patent possesses surprising and unexpected properties. Sepracor denies the remaining allegations set forth in paragraph 34.

35. The '673 patent makes the following assertions regarding the relative toxicity of the isomers of zopiclone:

> In a racemic product, it is known that, often, one of the two enantiomers is active and that an enhancement of the toxicity may be linked to this activity, the other enantiomer being both markedly less active or inactive and less toxic. For such products, the gain in activity does not compensate for the drawbacks due to an enhanced toxicity.
>
> In the case of zopiclone, it was found, surprisingly and unexpectedly, not only that the dextrorotatory isomer is approximately twice as active as the racemate while having a lower toxicity than that of the racemate, but that the laevorotatory isomer is both almost inactive and more toxic than the racemate.
>
> For example, when administered orally to mice, zopiclone possesses a toxicity (LD50 [sic LD50]) in the region of 850 mg/kg, whereas the dextrorotatory isomer has a toxicity in the region of 1.5 g/kg and the laevorotatory isomer possesses an LD50 [sic LD50] of between 300 and 900 mg/kg.

*'673 patent*, column 1, lines 35-52.

**RESPONSE:** Sepracor states that the document referenced in paragraph 35 speaks for itself as to form, content and legal effect. Sepracor denies the remaining allegations set forth in paragraph 35.

36. During prosecution of the '673 patent before the PTO, the '673 patent applicants submitted data, Declarations from scientific personnel, and attorney argument in support of the purported "surprising and unexpected" discovery that racemic zopiclone was more toxic than eszopiclone. The PTO Examiner relied on this data and argumentation in allowing the claims

which eventually issued in the '673 patent. The '673 patent applicants were in possession of information which contradicted their arguments and data, but they did not disclose the contradictory information to the PTO.

**RESPONSE:** Sepracor denies the allegations set forth in paragraph 36.

37. The '673 patent applicants presented data from a rat toxicity study conducted at a dose of 62.5 mg/kg. *Declaration of Bonnefoi*, Application Serial No. 08/493,945 and *Declaration of Doble*, Application Serial No. 09/124,651. According to the '673 patent applicants, at this dosage in rats, racemic zopiclone is more toxic than eszopiclone.

> Thus, racemic ZOPICLONE showed a statistically significant decrease in free T4 levels at 62.5 mg/kg/day, a dose four times lower than the dose at which a statistically significant decrease occurred for d-ZOPICLONE. Accordingly, it is clear that d-ZOPICLONE has a significantly lower toxicity than racemic ZOPICLONE.

*Amendment After Final Under 37 C.F.R. § 1.116*, November 17, 1997, Application Serial No. 08/493,946 [*sic*] at pages 7-8.

**RESPONSE:** Sepracor states that the documents referenced in paragraph 37 speak for themselves as to form, content and legal effect. Sepracor denies the remaining allegations set forth in paragraph 37.

38. The '673 patent applicants further argued to the PTO that this incredibly high dosage (corresponding to approximately 50 times the recommended dose in humans) corresponds to a drug abuse dosage and is therefore within the "conditions of use" of zopiclone. *Second Preliminary Amendment and Request than an Interference be Declared Under 37 C.F.R. § 1.607*, February 12, 1999.

**RESPONSE:** Sepracor states that the document referenced in paragraph 38 speaks for itself as to form, content and legal effect. Sepracor denies the remaining allegations set forth in paragraph 38.

39. In February 2001, the '673 patent applicants filed a Continued Prosecution Application "for the purpose of placing of record several items which are listed in the Information Disclosure Statement (IDS) filed concurrently herewith." *Preliminary Remarks*, February 5, 2001, Appln. Serial No. 09/124,651 at page 1. Among the items submitted was a one-page summary data sheet form Sepracor's IND for Lunesta® presenting the results of an

acute oral toxicity test in mice using racemic zopiclone and its isomers. According to the '673 patent applicants,

> None of this cited information related to toxicity is believed to adversely affect patentability of the allowed claim, but is brought to the Patent and Trademark Office's attention out of an abundance of caution in view of prosecution of the parent, in which issues relating to the effects of (+) zopiclone vs. the racemate were considered. In particular, claim 6 was allowed in view of the showing that the (+) zopiclone isomer possesses unexpectedly lower toxicity than the racemate *under conditions of use*. Under the dosages considered, the racemate was found to have significant non-lethal thyrotoxicity, in comparison to the (+) isomer. **In the acute toxicity data submitted herewith, the results were generally comparable for the (+) isomer and the racemate**. However, one of ordinary skill in the art would clearly understand that the results obtained upon administration of the massive and lethal dosages employed in the acute toxicity testing are not in conflict with the test results submitted and discussed in the Bonnefoi and Doble Declarations of record, which, as noted above, were based upon dosages corresponding to expected conditions of use in humans.

*Preliminary Remarks*, February 5, 2001, Appln. Serial No. 09/124,651 at page 2 (italics in original, **underlining** added).

**RESPONSE:** Sepracor states that the document referenced in paragraph 39 speaks for itself as to form, content and legal effect. Sepracor denies the remaining allegations set forth in paragraph 39.

40. The **emphasized** portion of the quote in paragraph 38 above is false. The data in the one-page summary from Sepracor's IND shows that the data presented is not "generally comparable" to the data presented in the parent application. In fact, under the conditions tested, the data in the one-page IND summary shows that the (+) isomer exhibits a lower Median Lethal Dose, and is more toxic, than the racemate – in direct contradiction to the data presented in the parent application (and the '673 patent specification). The '673 patent applicants were able to make this false statement without the examiner's knowledge because, although the '673 patent applicants knew the (S)-isomer was the (+) isomer, they did not indicate in the one-page summary which of the (S)- and (R)-isomers was the (+) isomer. The Examiner had no way of knowing from the one-page IND summary that the more toxic (S)-isomer was the (+) isomer.

**RESPONSE:** Sepracor states that the document referenced in paragraph 40 speaks for itself as to form, content and legal effect. Sepracor denies the remaining allegations set forth in paragraph 40.

41. The '673 patent applicants were in possession of additional data that contradicted the data presented in the '673 patent specification and the Bonnefoi and Doble Declarations, but did not submit that data to the PTO. The '673 patent applications possessed data in rats at dosages below 62.5 mg/kg which contradicted the data relied on for allowance – but they did not disclose the contradictory information to the PTO. On information and belief, during the time the '673 patent applicants were prosecuting the family of applications leading to issuance of the '673 patent, Sepracor conducted, or caused to be conducted, and completed a study entitled "Acute i.v. tox in Albino rats with zopiclone" ("the 1999 Rat Study"). On information and belief, a report of the study was finalized in February 1999. In the 1999 Rat Study, each of (+)-zopiclone ("eszopiclone" or "the S-isomer"), (-)-zopiclone ("the R-isomer") and racemic zopiclone ("the RS-" or "the racemate") were administered to rats and the median lethal dose (MLD) determined. According to the summary of the 1999 Rat Study in Sepracor's NDA for Lunesta®, the MLD in male rats was lower (more toxic) for (+)-zopiclone (1-10 mg/kg) than for the racemate (25-50 mg/kg). Pharmacology Review, NDA No. 21-476, pages 30-31 (publicly available FDA Approval Package). These toxic dosages are below the 62.5 mg/kg dosage used in the study presented to the PTO by Bonnefoi, Doble and the '673 patent applicants. This information contradicts the arguments and Declarations submitted to the PTO that the (+)-isomer has a lower toxicity than that of the racemate. In fact, this information supports the opposite conclusion, namely that the racemate is less toxic than the (+)-isomer (eszopiclone). The '673 patent applicants withheld the 1999 Rat Study from the PTO during prosecution of the '673 patent.

**RESPONSE:** Sepracor states that the document referenced in paragraph 41 speaks for itself as to form, content and legal effect. Sepracor denies the remaining allegations set forth in paragraph 41.

42. The '673 patent applicants were aware of highly material information that refuted, and was inconsistent with, their assertions of a "surprising and unexpected" result, and intentionally withheld that information from the PTO.

**RESPONSE:** Sepracor denies the allegations set forth in paragraph 42.

43. Based in part on the 1999 Rat Study and the data in the one-page IND summary, the Overall Toxicology Summary in the Lunesta® NDA concludes as follows: "Results from both species showed that the most toxic compound of all three based on mortality is the S-form." Pharmacology Review, Overall Toxicology Summary, NDA No. 21-476, page 28 (publicly

available FDA Approval Package). The "S-form" referred to in the NDA is eszopiclone, the dextrorotatory isomer of zopiclone and the subject of the claims of the '673 patent. The conclusion reached in the NDA directly contradicts the statements in the '673 patent specification, and supports the conclusion that the 1999 Rat Study was highly material to the patentability of the claims of the '673 patent.

**RESPONSE:** Sepracor states that the documents referenced in paragraph 43 speak for themselves as to form, content and legal effect. Sepracor denies the remaining allegations set forth in paragraph 43.

44. One or more of the '673 patent applicants knew that the statements in the '673 patent specification and file history regarding the relative toxicity of the isomers of zopiclone were false and misleading, because they knew the results of the 1999 Rat Study and/or the statements in the NDA.

**RESPONSE:** Sepracor denies the allegations set forth in paragraph 44.

45. The '673 patent applicants' pattern of misleading disclosures, selective disclosures, and/or non-disclosures with respect to highly material information demonstrates an intent to deceive or mislead the PTO. As such, the '673 patent is unenforceable and cannot be asserted against Wockhardt. Further evidentiary support for this allegation is likely to be identified after a reasonable opportunity for further investigation and discovery.

**RESPONSE:** Sepracor denies the allegations set forth in paragraph 45.

## PRAYER FOR RELIEF

Sepracor denies that Wockhardt is entitled to any relief on its counterclaims.

* * *

Sepracor denies each and every allegation of the counterclaims not expressly admitted or otherwise responded to above.

Dated: June 12, 2009

Respectfully submitted,

By: s/Charles M. Lizza

Charles M. Lizza
William C. Baton
SAUL EWING LLP
One Riverfront Plaza
Newark, NJ 07102
(973) 286-6700
clizza@saul.com
wbaton@saul.com

*Attorneys for Plaintiff*
*Sepracor Inc.*

*Of Counsel:*

Joseph M. O'Malley, Jr.
Bruce M. Wexler
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Eric W. Dittmann
Lynn M. Terrebonne
PAUL, HASTINGS, JANOFSKY & WALKER LLP
75 East 55th Street
New York, NY 10022
(212) 318-6000
josephomalley@paulhastings.com
brucewexler@paulhastings.com
davidconca@paulhastings.com
ericdittmann@paulhastings.com
lynnterrebonne@paulhastings.com